

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

UNITED STATES OF AMERICA ex rel.	§	
Braeden M. Hearrell,	§	
	§	
<i>Relator,</i>	§	
	§	
v.	§	CIVIL ACTION NO. 2:21-CV-00204-JRG
	§	
ALLERGAN, INC.,	§	
	§	
<i>Defendant.</i>	§	

MEMORANDUM OPINION AND ORDER

Before the Court is Defendant Allergan Inc.’s (“Allergan”) Motion for Summary Judgment on Relator’s Anti-Kickback Statute-Based FCA Claim (Dkt. No. 125) and Motion for Summary Judgment on Relator’s Off-Label Promotion Theory (Dkt. No. 124) (“the Motions”). On February 20, 2025, the Court heard oral argument on both Motions, which together are case-dispositive. Having considered the briefing and the parties’ oral arguments, the Court finds that the Motions should be and hereby are **GRANTED** for the reasons set forth herein.

I. LEGAL STANDARD

A motion for summary judgment is appropriate where “there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(a). A genuine issue remains if there is competent evidence that a reasonable jury could rely on to find for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). Such evidence must be construed in the light most favorable to the nonmovant. *Id.* at 255.

To prove a False Claims Act (FCA) claim, Relator needs evidence that Allergan made (1) “a false statement”; (2) “with the requisite scienter”; (3) “that was material”; and (4) “caused the

government to pay out money or to forfeit moneys due.” *U.S. ex rel. Ruscher v. Omnicare, Inc.*, 663 F. App’x 368, 373 (5th Cir. 2016). To prove its Anti-Kickback Statute (AKS) theory, Relator must also present evidence that Allergan: (1) paid “remuneration” (2) “to any person to induce such person ... to refer an individual to a person for the furnishing ... of any item or service for which payment may be made” under a Federal healthcare program; and (3) did so “knowingly and willfully.” *Id.* (quoting 42 U.S.C. § 1320a– 7b(b)(2)(A)).

II. DISCUSSION

A. Allergan’s Motion for Summary Judgment on Relator’s Anti-Kickback Statute-Based FCA Claim (Dkt. No. 125)

Relator alleges that Allergan made cash payments to doctors called Key Opinion Leaders (KOLs) in exchange for referrals to pediatric specialists. (Dkt. No. 125 at 1.) Relator alleges that such payments violated the AKS and caused pediatric specialists to submit false claims to Medicaid in violation of the FCA. (*Id.*)

In its briefing and at oral argument, Allergan argued that Relator lacks any evidence of an AKS violation. (*Id.* at 15.) In particular, Allergan emphasized that payments to KOLs for consulting and advisory services are legal, and that Relator has no evidence of any illegal remuneration amounting to a kickback. (*Id.*) For example, there is no evidence that the speaking events for which a KOL was paid were a sham or that the remuneration was for some other purpose, such as to induce referrals to pediatric specialists or to influence prescribing. (*Id.* at 15-17.)

The Court agrees with Allergan. Relator conceded at oral argument that he has no evidence that links *any* KOL payment to *any* referral or off-label prescription of Botox. (Dkt. No. 198 at 21:7-17; 23:2-9; 27:12-21.) Relator further conceded that he has no evidence from any doctor that Allergan paid them to prescribe Botox off-label. (*Id.*) Indeed, Relator failed to depose or obtain

documentary evidence from any KOL. As a result, there is a total absence of evidence within the record which supports Relator's allegation that Allergan's KOL payments were in exchange for referrals to pediatric specialists.

Accordingly, the Court finds that there is no material dispute of fact as to whether Allergan's KOL payments violated the AKS. Allergan's Motion for Summary Judgment on Relator's AKS-Based FCA Claim (Dkt. No. 125) should be and hereby is **GRANTED**.

B. Allergan's Motion for Summary Judgment on Relator's Off-Label Promotion Theory (Dkt. No. 124)

Relator also alleges that Allergan knowingly violated the FCA by promoting Botox off-label to treat chronic migraine patients under 18 years old. (Dkt. No. 124 at 1.)

In its briefing and at oral argument, Allergan argued that the Dallas Hospital claims at issue cannot be false because the claims explicitly disclose off-label Botox treatments for chronic migraine patients under 18 years of age. (*Id.* at 12-13.) Allergan also furnished un rebutted evidence from Relator's treating physician that Medicaid routinely reimburses for the use of Botox to treat chronic migraine for patients under 18, that the physician obtained prior authorization for each of the Botox claims she submitted to Medicaid, and that she would never prescribe this treatment unless she knew that Medicaid would reimburse this treatment. (Dkt. No. 194 at 6.)

Relator's sole argument appears to be that Allergan falsely represented to physicians that Botox is a safe and effective treatment for chronic pediatric migraine. (Dkt. No. 140 at 2.) The Court finds that argument unpersuasive. If the government knows the particulars of a claim and approves it, that claim cannot be fraudulent. It is undisputed that each Dallas Hospital claim at issue in this case discloses on its face the chronic migraine diagnosis, the Botox treatment, and the age of the patient. (*Id.* at 12-13.) It is also undisputed that Medicaid routinely reimburses for the

use of Botox to treat chronic migraine for patients under 18. (Dkt. No. 194 at 6.) Therefore, in the Court's view, there is no material dispute of fact that the claims at issue are not false.

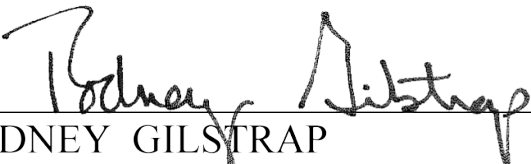
Accordingly, Allegan's Motion for Summary Judgment on Relator's Off-Label Promotion Theory (Dkt. No. 124) should be and hereby is **GRANTED**.

III. CONCLUSION

For the foregoing reasons, Allergan's Motion for Summary Judgment on Relator's AKS-Based FCA Claim (Dkt. No. 125) and Motion for Summary Judgment on Relator's Off-Label Promotion Theory (Dkt. No. 124) are **GRANTED**. Due to the case-dispositive nature of these Motions, the Court shall enter a Final Judgment in a separate Order pursuant to Federal Rules of Civil Procedure 58.

So Ordered this

Feb 28, 2025



RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE